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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/800,574	03/15/2004	Vanessa I. Chinea	200316497-1	1733

22879 7590 03/10/2008

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EXAMINER	
EBERHARD, JEFFREY S	

ART UNIT	PAPER NUMBER
1615	

NOTIFICATION DATE	DELIVERY MODE
03/10/2008	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/800,574	CHINEA, VANESSA I.	
	Examiner	Art Unit	
	JEFFREY S. EBERHARD	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 March 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-31* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-31* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *7/20/2005, 3/15/2004*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Abstract Objected to – Minor Informalities

The abstract of the disclosure is objected to because it does not allow the public to quickly determine the nature and gist of the technical disclosure nor include that which is new, and at 29 words, it does not meet the requirements (50-150 words) set forth at 37 CFR 1.72(b). Correction is required. See MPEP § 608.01(b).

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1 and 2 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The term "substantially accurately" in claim 1 is a relative term which renders the claim indefinite. The term "substantially accurately" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. The accuracy of a measurement is a function of many variables that describe a measured value relative to a reference value. The quantitative characterization of accuracy is typically prescribed by the users of the data that include the measurement, *e.g.*, FDA. Applicant recites "relative standard deviation," a

quantitative characterization of precision (the relative relationship of replicate measurements to one another) rather than accuracy, as a standard.

The terms "substantially high potent" and "substantially low dosage" in claim 2 are relative term which render the claim indefinite. The terms are not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. The concepts to which Applicant refers might more aptly be described as "highly concentrated" and "very low volume" or "picoliter volume," respectively. The instant Specification tends to support such a characterization, while "potency" and "dosage" imply reference to a specific compound (solute) and use of that compound.

Claim 11 recites the limitation "fluid jet drops." There is insufficient antecedent basis for this limitation in the claim. The balance of the claims in the instant application refer to a "fluid ejection device" that generates drops.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1, 2, 5, 7-25 and 27-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ellson, *et al.* (US 6,548,308 B2 and *Journal of the Association of Laboratory Automation* 2003, 8:29-34, referred to hereinafter as '308 and JALA, respectively).

The instant claims are directed to a method and a device for precise dispensing of very small volumes of (highly concentrated) solutions containing pharmaceuticals by means of fluid ejection.

Regarding claims 1, 2, 5, 8-14, 16-18, 23-25 and 27, Ellson '308 teaches a "method and device for generating droplets of [fluid]" (Abstract) which may comprise "pharmacologically active agents" (column 4, lines 43 to 45). The fluid(s) are acoustically ejected from one or more reservoirs then deposited on one or more substrates (Abstract) as droplets (≤1 pL, column 3, lines 53 to 55). While control of droplet size and volume is addressed throughout the '308 patent, Ellson '308 does not specifically teach precision of replicate volume measurements in terms of coefficient of variation (CV), or equivalently, relative standard deviation (RSD), nor does '308 specifically address the concentration of the solution to be transferred. JALA teaches a CV for replicate volume measurements at Table 2 (page 34) that is no more than 8% relative under less than ideal conditions (unknown solutions from multiple reservoirs), and less than 2% relative when volume dispensed is the only variable (replicate measurements from a single reservoir). JALA also teaches utility of acoustic droplet ejection (ADE) in situations where minimization of solvent volume relative to the amount of solute (*i.e.*, transfer of highly concentrated solutions) is critical to successful application of the technique (page 33, left column, second full paragraph). It would have been obvious to a person of ordinary skill in the art at the time the invention was made to have combined the method and device of the '308 patent with the statistical characterization of that device's precision taught by JALA when a demonstration of the precision of the highly concentrated fluid volume delivery is integral to the

successful use of the device in its intended application (*e.g.*, precise dispensing of concentrated solutions of pharmaceuticals).

Regarding claims 28-30, the Ellson art is discussed above, however neither the '308 patent nor the JALA paper teach the specific ranges characterizing volume measurement reproducibility recited in the instant claims. These volume measurements are a result effective variable that is a function of both the equipment used for dispensing and the solution being dispensed. The adjustment of particular conventional working conditions (*e.g.*, determining result effective amounts of the ingredients beneficially taught by the cited references) is deemed merely a matter of judicious selection and routine optimization which is well within the purview of the artisan of ordinary skill. Accordingly, manipulation of the dispensing equipment and dispensed solution would have been well within the purview of the person of ordinary skill in the art and no more than an effort to optimize results.

Regarding claims 19-22, the instant claims are drawn to a method and a device for precise dispensing of very small volumes of (highly concentrated) solutions containing pharmaceuticals by means of fluid ejection. The Ellson art teaches such a method and device. Applicant recites that the quantitative measurement of precision is to be obtained by a specific method (UV spectroscopy), however to the extent that this is a process limitation on volume measurement, it has not been established that volume measurement precision is different than the prior art. Ellson teaches volume measurement precision that appears to meet the limitations of the claims. The Office does not have the equipment to test whether or not the same result is obtained by determining measurement precision using UV spectroscopy as opposed to other art

accepted measurement techniques (e.g., fluorescence spectroscopy, JALA page 33, "Precision of Volume Transfer").

"[T]he PTO can require an applicant to prove that the prior art products do not necessarily or inherently possess the characteristics of his [or her] claimed product. Whether the rejection is based on 'inherency' under 35 U.S.C. 102, on '*prima facie* obviousness' under 35 U.S.C. 103, jointly or alternatively, the burden of proof is the same...[footnote omitted]." The burden of proof is similar to that required with respect to product-by-process claims. *In re Fitzgerald,* 619 F.2d 67, 70, 205 USPQ 594, 596 (CCPA 1980) (quoting *In re Best,* 562 F.2d 1252, 1255, 195 USPQ 430, 433-34 (CCPA 1977)).

Claims 3, 4, 6, 7, 15, 26 and 31 rejected under 35 U.S.C. 103(a) as being unpatentable over Ellson, *et al.* ('308 and JALA) and DrugBank (entry for Digoxin).

The Ellson art is discussed above, however it does not teach the use of the specific pharmaceutical digoxin tablets, its recommended dosing, or its solubility in various solvents. DrugBank teaches the cardiotonic glycoside digoxin, 4-[(3S,5R,8R,9S,10S,12R,13S,14S)-3-[(2R,4S,5S,6R)-5-[(2S,4S,5S,6R)-5-[(2S,4S,5S,6R)-4,5-dihydroxy-6-methyloxan-2-yl]oxy-4-hydroxy-6-methyloxan-2-yl]oxy-4-hydroxy-6-methyloxan-2-yl]oxy-12,14-dihydroxy-10,13-dimethyl-1,2,3,4,5,6,7,8,9,11,12,15,16,17-tetradecahydrocyclopenta[a]phenanthren-17-yl]-5H-furan-2-one (CAS# 20830-75-5) and its use and dosing in tablets. Solubility of digoxin is an inherent physical property that is directly related to the concentration of a digoxin solution that can be prepared. The adjustment of particular conventional working conditions (*e.g.*, determining result effective amounts of the ingredients beneficially taught by the cited

references) is deemed merely a matter of judicious selection and routine optimization which is well within the purview of the artisan of ordinary skill. Accordingly, manipulation of the amounts of solute and solvent in the preparation of solutions for dispensing or testing would have been well within the purview of the person of ordinary skill in the art and no more than an effort to optimize results.

Application Status and Examiner Contact Information

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey S. Eberhard, Ph.D. whose telephone number is (571) 270-3289. The examiner can normally be reached from 6:00 am to 2:00 pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael P. Woodward can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Jeffrey S. Eberhard, Ph.D.
Patent Examiner
Art Unit 1615

/Michael P Woodward/
Supervisory Patent Examiner, Art Unit 1615